REMARKS

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 are pending. In this response, claims 1, 5, 6, 12, 15, 16, 22, 26, 27, and 59 are amended and claims 7 – 11, 17 – 21, 28 – 54, 57, and 58 are cancelled. New claims 62 – 69 have been added. Applicant reserves the right to file divisional and other continuing applications directed to the withdrawn claims, as well as the subject matter disclosed but not claimed in the present application.

Independent claims 1, 12, and 22 have been amended to recite that the hydrogel in the patch comprises from about 5% to about 35% by weight polyvinylpyrrolidone and about 10% by weight of a local anesthetic. Support for the amendment to claims 1, 12, and 22 may be found in the specification, *e.g.*, at page 21, lines 1 – 9, and in Table 1 on page 31. Dependent claims 5, 15, and 26 were amended to remove non-elected subject matter. Support for new claims 62 – 64 may be found on page 21, lines 1 – 9. Support for new claims 65 – 69 may be found in Table 1 on page 31 and in the originally filed claims.

Election/Restriction

Claims 7 – 11, 17 – 21, and 28 – 53 have been cancelled, thus making this response to the Office Action complete.

Claim Rejections Under 35 U.S.C. § 102 Are Moot

Claims 1, 3 – 6, 22, 24 – 27, and 56 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,455,066 to Fischer *et al.* ("Fischer") for the reasons set forth on pages 2 and 3 of the Office Action. Claims 1, 3 – 6, and 12 – 16 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,469,227 to Cooke *et al.* ("Cooke") for the reasons set forth on page 3 and 4 of the Office Action. Claims 1, 3 – 6, 22, and 24 – 27 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Published U.S. Patent Application No. 2003/0027833 to Cleary *et al.* ("Cleary") for the reasons set forth on page 4 of the Office Action.

A claim is anticipated under 35 U.S.C. § 102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As stated in the response filed March 26, 2004, none of the references cited against the aforementioned claims disclose a sterile patch. Moreover, none

of the references disclose a sterile patch comprising a hydrogel, where the hydrogel comprises the recited amounts of polyvinyl pyrrolidone and of the local anesthetic. Thus, the references cited do not disclose each and every element recited in the claims, and do not anticipate them. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph Is Moot

Claim 57 stands rejected under 35 U.S.C. § 112, second paragraph because the use of the trade name "PEG" allegedly renders that claim indefinite. While not acquiescing to the Examiner's position, and simply in an effort to expedite the prosecution of this application, Applicant has cancelled claim 57. In light of the cancellation of claim 57, this rejection has been rendered moot. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103 Should Be Withdrawn

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, and 54 – 61 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cooke in view of U.S. Patent No. 5,405,366 ("Fox") or over Cleary in view of Fox. Applicant respectfully traverses these rejections.

Cooke discloses a non-occlusive adhesive skin patch that includes a porous backing and a therapeutic formulation that includes a medicament useful for relieving topical discomfort and a pressure sensitive adhesive (abstract and col. 1, lines 49 – 55). Cooke discloses that the pressure sensitive adhesive can include an adhesive, a polymer and a humectant, and that the adhesive can optionally be a gel (col. 6, lines 39 – 41). Regarding the polymer component, Cooke discloses a long list of "suitable" polymers that include polyvinyl pyrrolidone, but states that the preferred polymer is karaya (col. 6, line 63 to col. 7, line 12).

But, Cooke does not disclose or suggest a sterile patch comprising a polyvinylpyrrolidone-based hydrogel comprising a local anesthetic, as presently claimed. Moreover, Cooke does not teach or suggest a therapeutic formulation comprising a polyvinylpyrrolidone-based hydrogel comprising from about 5% to about 35% by weight polyvinylpyrrolidone, where the hydrogel comprises about 10% by weight of a local anesthetic, as presently claimed. In addition, Cooke does not teach or suggest a hydrogel comprising polyvinylpyrrolidone in the ranges recited by claims 55 and 56.

As pointed out in the response filed March 26, 2004, Cooke actually *teaches away* from the presently claimed invention by emphasizing that, in addition to the active

agent, the pressure sensitive adhesive includes an adhesive, a polymer and a humectant, as compared to the presently claimed polyvinylpyrrolidone-based hydrogel. Cook also teaches away from the claimed invention by stating that the preferred polymer is karaya.

Cleary does not disclose or suggest a sterile patch comprising a breathable backing coated with a polyvinylpyrrolidone-based hydrogel comprising from about 5% to about 35% by weight polyvinylpyrrolidone, and wherein the hydrogel comprises about 10% by weight of a local anesthetic, as presently claimed. Moreover, Cleary does not teach or suggest a polyvinylpyrrolidone-based hydrogel comprising polyvinylpyrrolidone in the ranges recited in claims 55 and 56. Cleary also does not disclose or suggest a package containing, or a method of using, such a patch, as presently claimed.

As Applicant previously pointed out, Cleary's compositions not only require a pharmaceutically acceptable nonliposomal carrier, but also require that the carrier comprise a monohydric alcohol, a penetration enhancer and a polymer. *See* abstract in Cleary. In fact, the required presence of a monohydric alcohol, a penetration enhancer and a polymer in the nonliposomal carrier is a primary object and alleged key finding of Cleary (pages 1 and 2, paragraph 0012, pages 5 and 6, paragraphs 0060, 0061, 0065 and 0067). Therefore, Cleary actually *teaches away* from the presently claimed invention, which includes a polyvinylpyrrolidone-based hydrogel comprising a local anesthetic by emphasizing that the carrier be nonliposomal and comprise a monohydric alcohol and a penetration enhancer, in addition to the polymer.

Fox does not cure the deficiencies of Cleary or Cooke. Fox discloses a non-stringy hydrophilic gel comprising an aqueous mixture of a radiation crosslinkable water-soluble polymer and an amount of at least one humectant effective to extend the in-use moisture retaining characteristics of the gel (abstract and col. 2, lines 60 – 65). Fox discloses that polyvinylpyrrolidone can be used as the water-soluble crosslinkable polymer (col. 6, lines 35 – 61) and that active ingredients such as lidocaine can be included into the gel (col. 20, lines 3 – 12).

But, Fox does not disclose or suggest a polyvinylpyrrolidone-based hydrogel comprising an anesthetic, as presently claimed. Certainly, Fox does not teach or suggest a polyvinylpyrrolidone-based hydrogel comprising from about 5% to about 35% by weight polyvinylpyrrolidone, wherein the hydrogel comprises about 10% by weight of a local anesthetic, as presently claimed. Moreover, Fox does not teach or suggest a polyvinylpyrrolidone-based hydrogel comprising polyvinylpyrrolidone in the ranges recited

in claims 55 and 56.

Like Cleary and Cooke, Fox *teaches away* from the presently claimed invention when Fox emphasizes the importance of a humectant for the prevention of crosslinking of the hydrophilic polymer. *See* col. 3, lines 18 – 46 and col. 6, lines 6 – 13. The presently claimed invention does not include a humectant as an essential component.

As illustrated by case law and the Manual of Patent Examining Procedure (May, 2004, "*MPEP*"), four basic considerations must be made when applying obviousness rejections: (A) the claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) there must be a reasonable expectation of success. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986); *MPEP* § 2141. Applicant respectfully submits that these requirements have not been met.

First, the Examiner should re-consider the claimed invention as a whole. For example, the rejected claims now all recite the feature that the polyvinylpyrrolidone-based hydrogel comprises from about 5% to about 35% by weight polyvinylpyrrolidone, wherein the hydrogel comprises about 10% by weight of a local anesthetic. Cleary, Cooke and Fox, whether alone or in combination, do not disclose or suggest the limitations recited in the amended claims.

Second, while the Examiner identifies individual features disclosed in the references, the Examiner has failed to consider the cited references as a whole. *Jones v. Hardy,* 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed.Cir.1984). For example, the Examiner fails to consider that Cleary's compositions not only require a pharmaceutically acceptable, nonliposomal carrier, but also require that the carrier comprise a monohydric alcohol, a penetration enhancer and a polymer; that Cooke emphasizes that the pressure sensitive adhesive includes an adhesive, a polymer and a humectant, in addition to the active agent; and that the alleged "surprising discovery" of Fox is the importance of a humectant to the hydrogel. Thus, when the art is properly considered as a whole, it is clear that Cleary and Cooke, alone or in combination with Fox, do not suggest the desirability of a polyvinylpyrrolidone-based hydrogel—especially one comprising from about 5% to about 35% by weight polyvinylpyrrolidone—comprising about 10% by weight of a local anesthetic, as presently claimed. Therefore, the references not only fail to render the pending claims

obvious, but actually teach away from the claimed invention because each reference provides teaching that would take away any motivation that one of ordinary skill in the art might have to achieve the present invention.

Third, the Examiner's rejection of the claims is based on impermissible hindsight. As the Examiner is aware, the requirement, in 35 U.S.C. § 103(a), "at the time the invention was made" is to avoid impermissible hindsight. MPEP § 2141.01. Thus, an Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." MPEP §2142. This is important, as "impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." *Id.* Consequently, when determining whether or not a claimed invention is obvious, one must cast his "mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

Based on the above principles, Applicant respectfully submits that the Examiner's rejection of the claims in view of the references is based on the use of impermissible hindsight, wherein the claimed invention is used as a blueprint for the selection and combination of prior art. This is particularly clear when one considers that not only the references fail to disclose or suggest every element of the presently claimed invention, but each reference actually contains teachings that would discourage and teach away from the claimed invention.

Fourth, Applicant respectfully submits that one of ordinary skill in the art, based on the disclosure in the references, would not have had a reasonable expectation of success in achieving the presently claimed invention even if he were to combine the references. In this regard, it is important to recognize the various and different disclosures reported in the references and the inherent unpredictability of pharmaceutical compositions and medical treatments. As discussed herein, Cleary emphasizes the importance of a nonliposomal carrier that includes a monohydric alcohol, a penetration enhancer and a polymer. Cooke emphasizes that the pressure sensitive adhesive includes an adhesive, a polymer and a humectant, in addition to the active agent, while Fox is focused on the importance of a humectant to the hydrogel. As such, one of ordinary skill in the art, reading these references, would not have had a reasonable expectation of success in achieving any polymer/adhesive/gel based topical formulation, not to mention the specific patch, patch

package and method currently claimed. *See, Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320 (Fed. Cir. 2000) ("that the inventors were ultimately successful is irrelevant to whether one of ordinary skill in the art, at the time the invention was made, would have reasonably expected success").

In sum, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. It is therefore respectfully requested that the rejection of the claims under §103 should be re-considered and withdrawn.

Conclusion

Applicant respectfully submits that all claim rejections have been overcome and that all pending claims are now in condition for allowance, early notice of which is earnestly solicited.

Respectfully submitted,

Date: Dec. 15, 2004

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